REMARKS

Claims 12, 14-15, and 39 are pending. Claims 1-11, 13, 16-38, and 40-48 have been canceled. Claim 14 was amended to clarify the nature of the subject matter regarded as the invention. No new matter has been added to these claims by way of these amendments. Reconsideration is respectfully requested.

Entry of Amendment

Applicants respectfully request entry of the present response to place the case in condition for immediate allowance or appeal.

Information Disclosure Statement

Applicants thank the Examiner for consideration of the Information Disclosure Statement previously submitted.

The Invention is Useful to Treat Prostate Cancer

Claims 12, 14–15, and 39 were rejected under 35 U.S.C. § 101 because the claimed invention allegedly is not supported by either a specific and substantial asserted utility or a well established utility. The Examiner alleged that the function of the protein was not known and thus claims to the protein were not supported by a specific and substantial assertion of utility.

Applicants traverse this rejection. The biological function of the protein in the cell is not relevant for determining if Applicants' asserted utility is sufficient to satisfy the utility requirement. Moreover, in view of the data provided in the specification as filed and during prosecution, one of ordinary skill in the art would not have a reasonable basis to doubt the specific and substantial nature of Applicants' asserted utility.

As a preliminary matter Applicants note that the Examiner has mischaracterized the utility Applicants rely upon to satisfy the utility requirement. "[A]n applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. § 101 and 35 U.S.C. § 112; additional statements of utility, even if not "credible," do not render the claimed invention lacking in

utility." M.P.E.P. § 2107.02, citing *Raytheon v. Roper*, 724 F.2d 951, 958, 220 USPQ 592, 598 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984). The Examiner does not get to choose which asserted utility is relied upon for patentability, the choice falls solely to Applicants. Here, as stated previously, Applicants assert that the protein comprising the amino acid sequence of SEQ ID NO:2 is a marker on cancerous prostate cells and is useful as a therapeutic target for antibodies directed against such cancer cells. Support for this assertion is found, for example, in the Abstract of the patent application.

The claimed protein is asserted as a useful target on cancer cells regardless of whether the protein is overexpressed relative to normal prostate cells. The claimed protein has other credible, substantial, and specific uses. Nevertheless, for the purposes of prosecution Applicants have asserted that the claimed protein is useful as a therapeutic target. The Examiner's discussion of issues regarding overexpression and issues regarding other possible utilities for the claimed subject matter is completely irrelevant to the issue of whether the pending claims satisfy the utility requirement because Applicants need only assert a single credible assertion of specific utility for the claimed invention to satisfy the utility requirement. As such, the Examiner's reliance on other, ancillary assertions of utility is in error.

The Examiner admits on page 3 of the Office Action that the specification discloses a nexus between the polynucleotide expression of the gene encoding the claimed protein (mRNA) and the presence of the mRNA in prostate cancer cells. The Examiner goes on to argue that applicants must show "some expression pattern that would allow the claimed polypeptide to be used in a diagnostic manner." *Id.* As stated above, Applicants assert that the protein is useful as a therapeutic target, not a diagnostic target. As such, the Examiner's arguments regarding the alleged difficulty of using the claimed protein for diagnostic purposes miss the mark. The claimed protein is useful as a therapeutic target and only arguments which go to this asserted utility are relevant.

It was argued in the Office Action that the claimed protein might be expressed in normal prostate cells as well as cancerous ones. The Examiner seems to believe that this state of affairs, if it exists, somehow undermines the asserted utility for the claimed protein. The Examiner is in error.

Regardless of whether the claimed protein is expressed in normal cells, one of ordinary skill in the art would not doubt the validity of Applicants' asserted utility.

To be useful as a therapeutic target, the claimed protein does not need to distinguish between cancerous and health prostate cells. Moreover, the claimed protein need not be overexpressed in cancerous prostate cells vs. normal prostate cells. All that need be shown for the claimed protein to be useful as required by the statute is that the protein be expressed by cancerous prostates cell. This is because once a diagnosis of prostate cancer is made (by methods that were readily available at the time the application was filed) the elimination of cancerous prostate cells becomes the paramount interest.

The Examiner seems concerned that antibodies directed against the claimed protein could not distinguish between normal prostate cells and cancerous prostate cells. This concern is misplaced. The loss normal prostate cells while eliminating cancerous prostate cells is inconsequential from the point of evaluating utility because the point of prostate cancer therapy is to eliminate prostate cancer cells. It would make no difference at all to one of ordinary skill in the art if normal prostate cells were killed while cancerous prostate cells are also killed. All that Applicants need to show to satisfy the utility requirement is that it is more likely than not that cancerous prostate cells will be killed using antibodies generated from the claimed protein. Those of ordinary skill in the art recognize that a human male can live without a prostate, a position supported by the common practice of surgically removing cancerous prostates from individuals diagnosed with prostate cancer. Thus, as long as it can be shown that the target protein is detectable by antibodies made against the claimed protein, utility is adequately supported.

Applicants have previously provided evidence which demonstrated that the claimed protein is expressed by cancerous prostate cells. Data supporting this point are found in the specification in the form of mRNA expression (*see* Figs. 4, 5, and 6) as well as in the Rule 1.132 declaration of Dr. Morrison, which was provided with the Oct. 12, 2005 response. Dr. Morrison's declaration clearly demonstrates that antibodies which bind to the claimed protein are capable of binding prostate cancer cells. This evidence is more than adequate to support Applicants' asserted utility.

In view of this evidence, one of ordinary skill in the art would have no reasonable basis to doubt the specific and substantial nature of Applicants' asserted use for the claimed protein.

Applicants have Provided Data Showing a Nexus between Detectable mRNA and Detectable Protein Expression

The Examiner insists that because Applicants have not shown a difference in expression levels of the claimed protein in normal prostate cells versus cancerous prostate cells, the utility requirement has not been satisfied. This argument is based on a number of scientific references.

"[T]he PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility." *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (citation omitted).

As previously explained, the cited references do not support the Examiner's case. At best the references support an argument which holds that one can have difficulty predicting absolute protein levels from detected mRNA levels. These references completely fail to make the case that one of ordinary skill in the art would reasonably doubt that detectable protein is present when detectable levels of mRNA are shown to be present.

Applicants note however, that the Examiner's argument is based on the faulty premise that overexpression of the claimed protein must be shown to satisfy the utility requirement. As previously explained, questions relating to expression levels of the claimed protein on normal cells are not relevant to the issue of utility because Applicants have demonstrated that the claimed protein is detected on cancerous prostate cells. This data was provided by Dr. Morrison's declaration. Applicants submit that the mRNA data provided in the specification is more than sufficient to allow one of ordinary skill in the art to conclude reasonably that the claimed protein is expressed in prostate cancer cells. The supplemental data only confirms the assertions made in the specification that the claimed protein is useful as a therapeutic target.

In view of Applicants asserted utility for the claimed invention, and the data submitted demonstrating that utility, the present rejection should be withdrawn.

The Pending Claims are Supported by an Enabling Disclosure

Claims 12, 14-15, and 39 were also rejected as allegedly failing the enablement requirement because an invention which lacks utility is not enabled. In view of the discussion above, Applicants have more than carried their burden to demonstrate that the claimed subject matter is supported by a credible, substantial, and specific utility. In view of this, the companion enablement rejection should be withdrawn.

The Board Decision in Ex part Ashkenazi, et al.

The Board of Patent Appeals and Interferences recently reversed an examiner how had made a lack of utility rejection with contours similar to those in this case. While the opinion published is not binding precedent on the Board, it is cited here to provide the Examiner some guidance as to how the Board is likely to rule on an appeal filed in this case.

In Ex part Ashkenazi the examiner rejected claims to an antibody which bound to a particular protein. The applicants in that case provided data that the protein at issue induced expression of c-fos in pericyte cells and that this action was inactive to the induction of angiogenesis. The examiner in the case disagreed, arguing that a specific biological role for the protein was not known and thus antibodies to the protein were merely the object of further research.

The Board agreed with applicants that the examiner failed to show a sufficient basis to challenge the asserted utility. The Board noted the data provided which supported the asserted utility and further undermined the relevance of each reference cited by the examiner in support of the rejection. For example, the examiner cited a paper by Orlandini et al. which alleged undermined the nexus between c-fos and angiogenesis. The Board found that the Examiner had overstated the conclusions of the paper, much like the Examiner in the present case has overstated the alleged lack of nexus between mRNA levels and protein levels.

Another example of the examiner overstated the conclusions in the cited references relates to the papers of Diaz-Flores and Ozerdem. The examiner argued that the role of pericytes cells in angiogenesis was not entirely elucidated. While the point might have had some scientific validity, the Board found that any missing teachings were not sufficient to provide reasonable doubt to one of ordinary skill in the art.

Just as in Ex part Ashkenazi, the Examiner here has failed to demonstrate a *prima facie* case. In view of this deficiency the Examiner is urged to withdraw the present rejections and pass the case to issuance.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. **511582000100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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